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No. 06-419

Supreme Court, U.S.
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In The

Supreme Court of the United States

PEDIATRIC SPECIALTY CARE, INC. *et al.*,

Petitioners,

v.

ARKANSAS DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Eighth Circuit

BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

Submitted on Behalf of:

ARKANSAS DEPARTMENT OF HEALTH AND HUMAN SERVICES; JOHN SELIG in his official capacity as Director of the ARKANSAS DEPARTMENT OF HEALTH AND HUMAN SERVICES; RAY HANLEY in his individual capacity as former Director of the DIVISION OF MEDICAL SERVICES OF THE ARKANSAS DEPARTMENT OF HEALTH AND HUMAN SERVICES; and ROY JEFFUS, in his individual capacity and his official capacity as Director of the DIVISION OF MEDICAL SERVICES OF THE ARKANSAS DEPARTMENT OF HEALTH AND HUMAN SERVICES

CHARLES R. HICKS, Chief Counsel
Counsel of Record
BRECK G. HOPKINS, Chief Deputy Counsel
DEPARTMENT OF HEALTH AND HUMAN SERVICES
P.O. Box 1437, Slot S260
Little Rock, Arkansas 72203
(501) 682-8934 Fax: (501) 682-8009

COCKLE LAW BRIEF PRINTING CO. (800) 225-6964
OR CALL COLLECT (402) 342-2831

QUESTION PRESENTED

For the last thirty-five years, health care practitioners have reviewed whether federally funded health care prescribed and provided by their peers is medically necessary and of a quality that meets recognized professional standards. Peer review is the linchpin of public health care integrity and sustainability.

To assure candid peer review, Congress enacted 42 U.S.C. § 1320c-9, which provides that any information obtained in the peer review process is confidential unless the Secretary of the United State Department of Health and Human Services adopts a regulation providing an explicit exception to the rule. The Secretary opted not to create an exception that singles out peer reviewers' identities for disclosure. The issue in this case is whether the Eighth Circuit Court of Appeals correctly held that the Secretary's regulation protecting peer reviewers' names from disclosure is a permissible construction of 42 U.S.C § 1320c-9(a)(2). *See* 42 C.F.R. §§ 480.101(b)(1) and 480.130-143.

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STATEMENT OF THE CASE

This case concerns Child Health Management Services ("CHMS") that are reimbursed under the Arkansas Medicaid Program. Petitioners know the identities of all the board-certified pediatricians who review CHMS medical necessity applications and have deposed each reviewer. They do not, however, have information connecting particular peer reviewers to specific reviews. It is this information that they contend must be disclosed notwithstanding federal law.

The Arkansas Department of Health and Human Services contracts with the Arkansas Foundation for Medical Care ("AFMC") to determine whether CHMS services requested by providers are medically necessary as required by 42 U.S.C. § 1320c-5(a)(1). AFMC is the federally certified utilization and quality control peer review organization in Arkansas. It engages local, practicing board-certified pediatricians to review and determine individual CHMS medical necessity applications. This review process is detailed in the AFMC's Brief in Opposition to Petition for Writ of Certiorari. Generally, a provider sends a request for the approval of services, which initially is reviewed by a nurse. If the nurse cannot approve all of the requested services, a Board-certified physician in the relevant field reviews the request. 42 U.S.C. § 1320c-3(a)(3)(D). If the reviewer determines that some or all of the services are not medically necessary, a second Board-certified physician will reconsider the decision upon request by the provider. *Id.* When both reviewing physicians agree that the requested care is unnecessary and should be denied, AFMC sends a proposed denial notice and rationale for review to Michael Moody, M.D., AFMC's Medical Director. Dr. Moody issues all denials.

Arkansas law permits providers and recipients to request administrative hearings. Ark. Code Ann. § 20-77-1704(b)(1). Hearings afford applicants an opportunity to demonstrate the medical necessity of the requested care through testimony and evidence. Administrative hearing decisions are subject to judicial review in a circuit court. Ark. Code Ann. § 25-15-212(a). Depending upon the issues raised, judicial review in circuit court is appealable to either the Arkansas Court of Appeals or the Arkansas Supreme Court. Ark. Const. amend. 80, § 11.

The Petition for Writ of Certiorari arises in an underlying case in which petitioners sued state officials and AFMC for damages. Petitioners assert that they are deprived of a federal right when AFMC physician-reviewers determine that requested CHMS services are not medically necessary. Petitioners argue that they must know the names of the nurses and physicians who reviewed each patient's request for CHMS services in order to vindicate that alleged right. The district court initially disagreed but later changed its mind and entered a preliminary injunction:

(1) Holding that the United States Department of Health and Human Service confidentiality regulations are invalid; and

(2) Directing the identification of peer reviewers who performed specific peer reviews.

The Eighth Circuit Court of Appeals reversed. The Court held that the Secretary's regulations are entitled to deference because the statute governing disclosure "specifically charges HHS with the duty to ensure peer review information is kept confidential through regulations aimed toward protecting 'the rights and interests of patients, health care practitioners, [and] providers of health care.'" *Pediatric*

Specialty Care, Inc. et al. v. Arkansas Department of Human Services et al., Appendix B to the Petition for Writ of Certiorari, at 9a (citing 42 U.S.C. § 1320c-9(a)(2)).

Petitioners Fail to State Grounds for Granting Writ of Certiorari

Supreme Court Rule 10(a)-(c) describes the three common bases for granting a writ of certiorari. Petitioners do not allege that their petition fits any of these criteria. Rather, they argue that the Eighth Circuit misapplied 42 U.S.C. § 1320c-9, which prohibits disclosure of any peer review information, and the federal regulations implementing that statute. Certiorari should not be granted because "[a] petition for writ of certiorari is rarely granted when the asserted error consists of . . . the misapplication of a properly stated rule of law." *See* Supreme Court Rule 10. In addition, there is no need to grant certiorari because the Eighth Circuit correctly applied 42 U.S.C. § 1320c-9, 42 C.F.R. § 480.101(b), and 42 C.F.R. § 480.130-480.143.

Medical Necessity Requirement

Medicaid pays for medically necessary care only. 42 U.S.C. § 1320c-5(a)(1); 42 U.S.C. § 1396a(a)(30)(A); 42 C.F.R. § 1004.10; 42 C.F.R. § 456.1. The Medicaid statute "confers broad discretion on the States to adopt standards for determining the extent of medical assistance, requiring only that such standards be 'reasonable' and 'consistent with the objectives of the Act.'" *Beal v. Doe*, 432 U.S. 438, 444 (1977). It is consistent with Medicaid objectives "for a state to refuse to fund *unnecessary* – though perhaps desirable – medical services." *Id.* at 444-45 (emphasis in original).

The Early and Periodic Screening, Diagnosis, and Treatment provisions of the Medicaid Act ("EPSDT") are no exception to the requirement that Medicaid payments are limited to medically necessary services. Under EPSDT, Medicaid eligible persons under age 21 must be furnished all *medically necessary* care and treatment meeting the EPSDT definition and identified by an EPSDT health care screening. 42 U.S.C. § 1396d(r)(5); 135 Cong. Rec. S. 6899, 6900 (daily ed. June 19, 1989) (statement of Sen. Chafee) (EPSDT requires states to provide "any medically necessary service identified as necessary through the EPSDT Program."); Arkansas Child Health Management Services ("CHMS") Medicaid Manual, § 142 (8) ("All services provided must be based on medical necessity."). CHMS services are required under EPSDT when properly prescribed and medically necessary for eligible recipients.

Background of Medicaid's Peer Review System

In 1972, Congress was alarmed that Medicare and Medicaid costs were rising rapidly despite laws prohibiting unnecessary care and requiring utilization reviews. Congress attributed the problem in part to increased utilization of health services that were "probably not medically necessary." S. Rept. 92-123 at p. 254. The legislative history states: "Aside from the economic impact the committee is most concerned about the effect of over utilization on the health of the aged and the poor." *Id.* Limiting payments to medically necessary services minimizes risk to patients and avoids wasting valuable resources that are needed elsewhere. *American Hospital Ass'n v. Bowen*, 834 F.2d 1037, 1041 n.1 (D.C. Cir. 1987) (quoting S. Rep. No. 97-494, 97th Cong., 2d Sess. 41 (1982), *reprinted in* 1982 U.S.C.C.A.N. 781, 817). Accordingly, Congress authorized

peer review organizations such as AFMC to control utilization.

Peer review is designed to have physicians "judge whether services ordered by other physicians are necessary." S. Rept. 92-123 at p. 256. Peer review is a recognized method of assuring that taxpayer funds are not wasted on unnecessary care, and it is a cornerstone of publicly funded medical assistance. *See generally*, 42 U.S.C. § 1320c.

State contracting with utilization and quality control peer review organizations are deemed to meet their Medicaid requirements for medical and utilization review for those services or providers subject to review under the contract. 42 U.S.C. § 1396a(d); 42 C.F.R. § 456.2. Arkansas fulfills its CHMS utilization review obligations by contracting with AFMC, a federally certified[1] utilization and quality control peer review organization, to peer-review CHMS medical necessity.

General Principles of Peer Review Confidentiality

Peer review, whether conducted by a hospital peer review committee or a federal utilization and quality control peer review organization established under 42 U.S.C. § 1320c, is uniformly conducted without disclosing the names of peer reviewers. That is because no peer review system can exist and operate effectively unless:

> (1) Peer review organizations are able to enlist practitioners to serve as peer reviewers; and

[1] *See* 42 U.S.C. § 1320c-2.

(2) Peer reviewers are free from influences that would deter them from issuing frank and accurate opinions.

Courts interpreting other peer review confidentiality statutes have recognized these policy concerns. *See, e.g., Virmani v. Presbyterian Health Servs. Corp.*, 515 S.E.2d 675, 685-686 (N.C. 1999) (stating that the purpose of a North Carolina statute shielding medical review committee records and materials is to "promote candor and frank exchange in peer review proceedings" despite the potential impairment of access to evidence); *Jenkins v. Wu*, 468 N.E.2d 1162, 1168 (Ill. 1984) (interpreting a similar Illinois act and noting that the legislature was motivated to encourage physicians to serve on peer review committees).

The only relevant evidence in this case supports the reasoning behind these policy goals. David Wroten, Assistant Executive Vice President of the Arkansas Medical Society, testified that sweeping away the traditional confidentiality accorded to peer reviewers would eliminate the physician-based utilization control peer review system created by Congress. He maintained that pressure from prescribing physicians whose prescriptions were deemed unnecessary, from others (*e.g.*, patients and their families), from the press, coupled with the time away from the physician's practice to respond to complaints and attend trials and depositions, would dissuade practicing physicians from participating in medical necessity reviews. T. 508, appendix App. 1-4. Mr. Wroten testified that if AFMC disclosed the names of physician reviewers as demanded by the petitioners, "no physician would agree to participate in the process." *Id.* at App. 2. His testimony is unrebutted.

The Eighth Circuit Decision

Petitioners argue that the Eighth Circuit misapplied 42 U.S.C. § 1320c-9(d) by failing to recognize the distinction between utilization control and quality of care reviews. Petitioners' argument misses the point, because the Eighth Circuit opinion does not hinge on this section of the statute. Rather, the Eighth Circuit relied upon 42 U.S.C. § 1320c-9(a) and federal regulations providing that:

> (1) Information identifying a peer reviewer is confidential. 42 C.F.R. § 480.101(b); and
>
> (2) Physician reviewer identities may not be disclosed except with the reviewer's written permission. 42 C.F.R. § 480.133(a)(2)(iii).

Given that the Secretary's regulations explicitly and unambiguously protect peer reviewers' identities regardless of the function performed, the only legitimate issue is whether the regulations are valid. The Eighth Circuit recognized this as the issue on appeal, and it correctly applied section 1320c-9(a).

DISCUSSION

The Secretary's Regulation Is a Permissible Construction of the Statute and Is Entitled to Deference

To be valid and entitled to deference, the regulations must be based on a permissible construction of the statute. *Chevron U.S.A. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984). We therefore turn to 42 U.S.C. § 1320c-9, captioned "Prohibition Against Disclosure of Information," which provides in part that:

> Any data or information acquired by any such organization in the exercise of its duties and functions shall be held in confidence and shall not be disclosed to any person except
>
> . . .
>
> (2) in such cases and under such circumstances as the Secretary shall by regulations provide to assure adequate protection of the rights and interests of patients, health care practitioners, or providers of health care.

42 U.S.C. § 1320c-9(a)(2).

Section 1320c-9(b) provides that: "An organization having a contract with the Secretary under this part shall provide in accordance with procedures and safeguards established by the Secretary, data and information . . . which may identify specific providers or practitioners as may be necessary" to assist federal and state agencies in identifying fraud and abuse, public health risks, and for purposes of provider licensing and certification. Disclosure of reviewers' identities in medical necessity reviews is conspicuously absent from the list of permitted disclosures.

Under § 1320c-9(a)(2) the Secretary is given authority to adopt regulations to protect the rights and interests of "patients, health care practitioners, or providers of health care." Peer reviewers are of course included within the protections of this statute because they are by definition health care practitioners. Otherwise they would not be "peers" of other health care practitioners. *See* 42 U.S.C. § 1320c-1, which defines a utilization and quality control peer review organization as an entity:

> " . . . composed of a substantial number of the licensed doctors of medicine and osteopathy engaged

> in the practice of medicine or surgery in the area and who are representative of the practicing physicians in the area. . . ."

Another relevant statute, 42 U.S.C. § 1320c-3(a)(7), states that peer reviewers must be:

> persons who are practitioners of, or specialists in, the various areas of medicine (including dentistry, optometry, and podiatry, or other types of health care, which persons shall, to the maximum extent practicable, be individuals engaged in the practice of their profession within the area served by such organization. . . .

As "health care practitioners," peer reviewers are entitled to all the protections of 42 U.S.C. § 1320c-9 and the regulations adopted by the Secretary thereunder. It necessarily follows that the Secretary's regulation protecting peer reviewers is based on a statutory construction that is not merely permissible; it is the only construction that gives effect to Congress's intent. Therefore the regulation is entitled to deference under *Chevron*.

Section 1320c-9 provides that utilization and quality control peer review organizations must disclose *no information* unless the disclosure is permitted under a regulation adopted by the Secretary. 42 U.S.C. § 1320c-9(a). Petitioners do not dispute that peer reviewer identities are "information acquired by [AFMC] in the exercise of its duties and functions." *Id.* Standing alone this protects peer reviewer identities unless Congress enacted an exception in § 1320c-9(b)(1) making that information public or the Secretary adopted a regulation under § 1320c-9(a)(2) creating an exception that allows publication of peer review identities. Petitioners do not argue that Congress

or the Secretary created any exception permitting disclosure of the identities of peer reviewers.

They claim that because there is not a second disclosure prohibition specifically directed to peer reviewer identities, those identities must be disclosed. This approach turns the statute upside down. In other words, the petitioners would have this Court hold that a statute *prohibiting disclosure* of "any data or information" acquired by AFMC *mandates disclosure* of peer reviewer identities. No rationale for this contradiction is contained in the Petition for Writ of Certiorari.

Petitioners' analysis supposes that § 1320c-9 is silent about peer reviewer information acquired in the course of utilization control peer reviews. However, § 1320c-9 applies to "all information" in the possession of the organization, to all "functions under a contract entered into under this part," and to the peer review organization's "duties and functions." Accordingly, § 1320c-9 is all encompassing.

Petitioners rely on one case relating to disclosure by utilization and quality control peer review organizations, namely, *Public Citizen, Inc. v. United States Dept. of Health and Human Servs.*, 332 F.3d 654 (D.C. Cir. 2003). However, *Public Citizen* is wholly distinguishable. That case concerned quality of health care complaints made to peer review organizations. 42 U.S.C. § 1320c-3(a)(14) requires that such organizations inform complainants of the outcomes of their complaints. In *Public Citizen*, the Secretary's regulation (which pre-dated the statute) instructed peer review organizations to withhold outcomes and tell complainants only that their complaints had been resolved. The Secretary's regulation was therefore not a permissible construction of the statute. Accordingly, *Public*

Citizen held that under those circumstances no deference was owed to the Secretary's regulation.

Section 1320c-9 contains no language contrary to the Secretary's regulation. Consequently, there is no basis to compare the case to *Public Citizen* or to deny *Chevron* deference to the regulation.

There Is No Need to Disclose the Identities of Peer Reviewers

Peer reviewers must meet the federal qualifications set out in 42 U.S.C. § 1320c-3(a)(7) before they can judge medical necessity. Because they are judges, not witnesses, there is no constitutional right to subpoena peer reviewers to medical necessity hearings. *Featherston v. Stanton*, 626 F.2d 594 (7th Cir. 1980). Furthermore, administrative hearings are not "truly adversary" proceedings. *Williams v. Scott, Director*, 278 Ark. 453, 455 (1983). They are not forums to pit doctor against doctor; rather, the hearings afford applicants an opportunity to present testimony and evidence to carry the burden of proving that the requested care is medically necessary. *Id.*

The review processes already works as Congress intends. Nevertheless, petitioners want peer reviewers to be subject to subpoena every time they make a medical necessity judgment. The result would be to place the judge, not the judgment, on trial.

Petitioners cannot claim that they are unable to identify a physician to testify about peer reviews. Dr. Michael Moody is ultimately responsible for each AFMC peer review medical necessity decision and is named on each denial. In reality, the petitioners want to undermine

the peer review process by compelling the identities of the reviewers. They know that it is extraordinarily difficult for one physician to publicly criticize another. They also know that if health care practitioners face possible harassment in retaliation for their candor and often are forced away from their practices to testify, most physicians would decline to participate in public health care peer review in any meaningful way. These are precisely the concerns that compelled Congress to provide for peer review confidentiality.

CONCLUSION

In summary, the Eighth Circuit Court of Appeals correctly applied the statutes and regulations controlling the disclosure of peer reviewers' names. The petitioners failed to provide any reason for this Court to grant the Petition for Writ of Certiorari, and indeed there is none.

Respectfully submitted,

CHARLES R. HICKS, Chief Counsel
Counsel of Record
BRECK G. HOPKINS,
Chief Deputy Counsel
DEPARTMENT OF HEALTH AND
HUMAN SERVICES
P.O. Box 1437, Slot S260
Little Rock, Arkansas 72203
(501) 682-8934 Fax: (501) 682-8009

Attorneys for Petitioners

Appendix

Excerpts from April 5, 2004 Motion Hearing

DAVID WROTEN, ARKANSAS DHS DEFENDANTS' WITNESS, DULY SWORN

DIRECT EXAMINATION

BY MR. HOPKINS:

Q. What's your name?

A. David Wroten.

Q. What is your occupation, Mr. Wroten?

A. I'm the assistant executive vice-president for the Arkansas Medical Society.

Q. How long have you held that position?

A. 20 years.

Q. What is the Arkansas Medical Society?

A. It's the professional association that represents the physicians of Arkansas.

Q. And you represent that association, so, in turn, you represent the physicians?

A. Yes, I do.

Q. Does the Medical Society advocate on behalf of physicians in connection with governmental programs such as Medicaid?

A. Yes, we do.

Q. Are you generally familiar with the Medicaid program because of your advocacy role?

A. Very familiar, yes.

* * *

Q. Sure. Isn't it true that the Arkansas Medical Society has tried to garner the support of its individual doctor members to oppose the plaintiffs' claim in this case that the doctors and nurses employed by AFMC should be disclosed in these denial letters that are issued so that they can be subpoenaed and questioned on appeal?

A. Well, we are opposed to those physicians' names being presented, yes.

Q. Why?

A. Because if in very case that comes up and every trial that comes up or every judicial hearing or administrative hearing, if the names of the physician reviewers were to be made public, then the bottom line is, no physician would agree to participate in the process.

THE COURT: Why?

BY MR. BOWEN:

Q. Why?

A. Because it's time out of their practice, it's pressure, peer pressure from others, peer pressure from the local press: You deny the service? How dare you deny a service? We know that family, and we feel like that family is needy and that they need help.

THE COURT: The Medical Society feels like that this secret review is preferable?

THE WITNESS: Well, I don't believe it's a secretive review, but the identification of the reviewers is. They are all board certified in the specialty for which they review. We feel strongly that if that protection were not there, and that protection has been handed down in the statutes that created the peer review process in the first place, then physicians would not want to participate in the process.

* * *

THE COURT: Maybe it could be explained to me, but I really have trouble with that concept. I have a hard time understanding how the opinions can be tested if the identities are now known. But I'll let the lawyers work on that.

* * *

THE COURT: Let me ask again, why do the doctors not want to be identified?

THE WITNESS: If the physicians were identified in every single case, and I think there was testimony presented earlier that they do some 8,000 reviews a month, and if the physicians, every physician that had ever reviewed a medical record and rendered a decision or denied a service based on that medical record, if their names became public or generally made public, they just simply would not participate.

THE COURT: Why?

THE WITNESS: For fear of reprisals.

THE COURT: By who?

THE WITNESS: From patients, from attorneys. They would be in court all the time.

THE COURT: How would a lawyer reprise against them?

THE WITNESS: Do what?

THE COURT: How would a lawyer reprise against them?

THE WITNESS: They would bring them in court and have them testify in every case –

THE COURT: And that's a reprisal?

THE WITNESS: To a physician who is in private practice, which most of these physicians are, any time out of their practice to spend a day in court is a tremendous – you know, a tremendous impact.